

### **REMARKS/ARGUMENTS**

Claims 15-17, 21-36 and new claim 37 are under examination in this Application. Claims 16, 17 and 31 have been cancelled. The Final Office Action mailed on January 5, 2009, includes the following objections and rejections:

1. Claim 28 is objected to.
2. Claims 15-17 and 21-29 are rejected under 35 U.S.C. 112, first paragraph.
3. Claims 15-17 and 21-36 are rejected under 35 U.S.C. 103(a).

All amendments to the claims are fully supported by the specification as originally filed. Specifically, the present invention provides a nutritional supplement that provides a nutritionally affective amount of a composition capable of suppressing the effects of translocase deficiency. Specifically, paragraph [0013] of the specification as filed states, "In a preferred nutritional supplement, the compound or derivative thereof is capable of being broken down by normal 13-oxidation in humans to methylbutyric acid. In another preferred nutritional supplement, the compound or derivative thereof is capable of being broken down by normal J3-oxidation in humans to isovaleric acid." As a result, the specific compositions of the instant invention provides a nutritional supplement in an amount capable of suppressing the effects of translocase deficiency, i.e., a nutritionally affective amount. In addition, the specifications provides indications of the amount of the composition that is necessary to provide an affect, e.g., [0077-78].

#### ***Claims 28 objection***

Applicant respectfully submits that claim 28 has been amended to overcome the objection and requests withdrawal of the objection.

***Claims 15-17 and 21-29 are rejected under 35 U.S.C. § 112, first paragraph.***

Applicant respectfully submits that the present application is enabled to support claims 15-17 and 21-29 as amended and fully complies with 35 U.S.C. § 112 first paragraph.

***Claims 15-17 and 21-36 are rejected under 35 U.S.C. § 103(a)***

The Action also rejects claims 15-17 and 21-36 are rejected under 35 U.S.C. 103(a) as being as being unpatentable over Odie, et al. (Journal of Nutrition, 1991, Vol. 121, pages 605-614; provided by Applicant, hereafter referred to as “Odie”), in view of Ajinomoto (JP 52015834A (provided by Applicant) hereafter referred to as “Ajinomoto”) and Jandacek (US Patent No. 4,753,963 hereafter referred to as “Jandacek”). Applicant is fully aware of the above listed art as it was referenced by the Applicants, and respectfully submit that the instant invention and the combination of cited art are different. As a result the instant inventions is not rendered obvious by the suggested combination.

The combination fails on all counts to establish obviousness. To establish a *prima facie* case of obviousness there must be: (1) some suggestion or motivation either in the reference itself, or within the knowledge generally available to one of ordinary skill in the art, to modify the reference; (2) a reasonable expectation of success, and (3) a teaching or suggestion in the prior art reference of all of the claim limitations (MPEP § 2143). *In re Vacek*, 947 F. 2d. 488 (Fed. Cir. 1991). The combination fails on all counts.

The combination of references fails to teach each and every limitation of the instant invention. Specifically, the combination fails to disclose a method of suppressing the effects of translocase deficiency of a prematurely-born human infant by identifying an infant suspected of having a translocase deficiency; and administering to an infant suspected of having a translocase deficiency a composition comprising a nutritionally effective amount of a n-heptanoic acid to treat the translocase deficiency.

Odle discloses the use of medium-chain triglycerides by neonatal piglets where the chain length of even- and odd-carbon fatty acids and apparent digestion/absorption and hepatic metabolism. However, Odle fails to teach a method of suppressing the effects of translocase

deficiency of a prematurely-born human infant. Odle fails to disclose administering to said human infant a nutritionally effective amount of a compound. Odle fails to disclose identifying an infant suspected of having a translocase deficiency. Odle fails to disclose administering to an infant suspected of having a translocase deficiency a composition. There is NOTHING in Odle that relates to the treatment of humans having a translocase deficiency. There is nothing in Odle that indicates that a seven-carbon fatty acid is safe for consumption by humans or has any particular nutritional benefit to humans.

The addition of Ajinomoto does not cure this deficiency. Arguably, Ajinomoto discloses (but fails to enable) a food composition having triheptanoin or trinonanoin. However, Ajinomoto fails to disclose a composition comprising a nutritionally effective amount of a n-heptanoic acid to treat the translocase deficiency. There is NOTHING in Odle that relates to the treatment of humans having a translocase deficiency. At the very most Ajinomoto may disclose a food stuff having triheptanoin, where the food stuff used may include proteins (e.g. milk casein, soybean protein), oils (e.g. soybean oil, sunflower oil, corn oil), carbohydrates (e.g. glucose, fructose, maltose, sucrose, dextrin, corn starch, xylitol, sorbitol), vitamins and minerals. Ajinomoto states that the additives are not necessarily pure e.g. may contain a small amount of fatty acids. As such, the combination still fails to teach each and every limitation.

The further addition of Jandacek still does not cure this deficiency. Jandacek fails to disclose administering to said human infant a nutritionally effective amount of a compound. Jandacek does not disclose identifying an infant suspected of having a translocase deficiency nor does Jandacek disclose the administering to an infant suspected of having a translocase deficiency a composition comprising a seven carbon fatty acid selected from triheptanoin or n-heptanoic acid or derivatives thereof. As such, the combination still fails to teach each and every limitation.

As a result, the combination of Odle and Ajinomoto and Jandacek fails to disclose a method of suppressing the effects of translocase deficiency of a prematurely-born human infant. The combination fails to disclose identifying an infant suspected of having a translocase deficiency and fails to disclose administering to an infant suspected of having a translocase deficiency a composition comprising a nutritionally effective amount of a n-heptanoic acid to treat the translocase deficiency

Furthermore, it is improper to combine Jandacek with Odle and Ajinomoto since Jandacek is at the very most non-enabling art. Jandacek is not enabling art because it is merely a broad listing of possible different compounds does not place seven carbon fatty acid selected from triheptanoin or n-heptanoic acid or derivatives thereof in possession of the public. See additionally, *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 586 F. Supp. 1176, 1221, 222 USPQ 863 (D. Kan. 1984). *af'd in part & rev'd in pan*, 772 F.2d 1570, 227 USPQ 177 (Fed. Cir. 1985) ("**a printed publication which merely names a new compound or substance is insufficient as an anticipation.**") (emphasis added); *Air Products & Chem., Inc. v. Chas. S. Tanner Co.*, 219 USPQ 223 (D. S.C. 1983) ("a prior art reference which contains a **broad general disclosure requiring guessing, testing, speculation or 'picking and choosing' from an encyclopedic disclosure will not anticipate.**") (emphasis added). The only examples, presented by Jandacek are triglyceride with 3 even numbered carbon chains attached. Specifically, an 18 carbon chain and two 8 carbon chains attached to a glycerol, see Column 4, lines 12-13 of Jandacek below:

The synthesis of 2-linoleoyl-1,3-dioctanoin according  
to the present invention is described as follows:

The examples in Jandacek are triglyceride, i.e., glycerol that is esterified with three even chain fatty acids, i.e., a 18 carbon chain and 2 8 carbon chains, see above. Jandacek doesn't even teach/enable a triglyceride with an odd carbon fatty acid of seven or less carbons. As a result, the deficiencies in the Odle are not cured by the addition of Ajinomoto and Jandacek.

The Office Action has not met its burden to establish obviousness. The combination of Odie and Ajinomoto and Jandacek fails to teach a method of suppressing the effects of translocase deficiency of a prematurely-born human infant by identifying an infant suspected of having a translocase deficiency; and administering to an infant suspected of having a translocase deficiency a composition comprising a nutritionally effective amount of an isolated and purified n-heptanoic acid; triheptanoin; 4-methylhexanoate, 4-methylhexenoate, 3-hydroxy-4-methylhexanoate, 5-methylhexanoate, 5-methylhexenoate and 3-hydroxy-5-methylhexanoate, to treat the translocase deficiency wherein the compound is adapted for consumption in one or more doses of between 15 and 40% of the dietary caloric requirement for said infant for 24 hours to provide the infant nutrition from odd carbon fatty acid  $\beta$ -oxidation metabolism.

*KSR Int'l. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007), the Court stated that "a patent composed of several elements **is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.** Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a **reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.** This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." Id. at 1741 (emphasis added).

As the PTO recognizes in MPEP § 2142:

*... The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness...*

The combination fails to teach a nutritionally effective amount of an n-heptanoic acid and triheptanoin compositions to treat the translocase deficiency in a human infant. The combination fails to teach the specific compounds: 4-methylhexanoate, 4-methylhexenoate, 3-hydroxy-4-methylhexanoate, 5-methylhexanoate, 5-methylhexenoate and 3-hydroxy-5-methylhexanoate. The combination fails to disclose identifying an infant suspected of having a translocase deficiency and the combination fails to disclose administering to an infant suspected of having a translocase deficiency a composition.

Accordingly, Applicants respectfully submit that claims are not obvious over the combination of Odle and Ajinomoto and Jandacek, and are, therefore, allowable under 35 U.S.C. § 103(a). Applicants respectfully request that the rejection of claim be withdrawn.

### CONCLUSION

In light of the foregoing, Applicant submits that claims 15, 21-30 and 32-37 are in condition for allowance, and an early Notice of Allowance of all pending claims is respectfully solicited. Please find a Request for Continued Examination and the associated fee. This paper is being filed with all required fees; however, if any additional fees are necessary the Commissioner is hereby authorized to charge any fees, including those for an extension of time, to Chalker Flores, LLP's Deposit Account No. 50-4863.

If the Examiner has any questions or comments, or if further clarification is required, it is requested that the Examiner contact the undersigned at the telephone number listed below.

Dated April 6, 2009

Respectfully submitted,



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